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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CARMEN OTERO and ABBEY LERMAN, as individuals, and on behalf of other members of the general public similarly situated,

Plaintiffs,

v.

ZELTIQ AESTHETICS, INC., a Delaware corporation; and DOES 1-10, inclusive,

Defendants.

Case No.: 2:17-cv-3994 DMG (MRWx)
Hon. Dolly M. Gee

FIRST AMENDED CLASS ACTION COMPLAINT FOR:

(1) Violations of California's Consumers Legal Remedies Act;
(2) Violation of False Advertising Law, California Business & Professions Code § 17500; and
(3) Violation of Unfair Competition Law, California Business & Professions Code § 17200 *et seq*.

Complaint Filed: April 26, 2017
L.A.S.C. Case No. BC659192
Notice of Removal Filed: May 30, 2017

DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiffs Carmen Otero and Abbey Lerman ("Plaintiffs") bring this action for themselves and on behalf of all persons in the United States who, at any time in the last four years prior to the filing of this complaint, purchased one or more CoolSculpting procedures. "CoolSculpting" consists of several medical devices manufactured, marketed, distributed, and sold by Zeltiq Aesthetics, Inc. and DOES 1-10 ("Zeltiq" or "Defendants") used in performing non-surgical cosmetic procedures.

2. This case arises out of the unlawful, false, misleading, and deceptive marketing practices used by Defendants regarding CoolSculpting. Defendants have deceptively led customers to believe that they were purchasing, for a premium price, medical treatments that have gone through the rigorous FDA-approval process, with all the safety and efficacy that this implies. Yet, Defendants' CoolSculpting system has not received premarket FDA approval ("PMA") but rather, has merely received 510(k) premarket notification clearance ("510(k)"), a crucial distinction that Defendants misrepresent to consumers. PMA requires the independent trials and testing of the FDA, and constitutes the FDA's endorsement as to the safety and effectiveness of a product. In contrast, 510(k) clearance merely entails a finding by the FDA that a medical device is substantially equivalent to a pre-existing device marketed before the enactment date of the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act (FDCA).

3. To increase revenue and gain an advantage over competitors, Defendants imply to consumers that their 510(k) premarket notification clearance constitutes the FDA's endorsement as to the safety and effectiveness of a product. This conduct violates regulations promulgated by the FDA pursuant to the FDCA, which state:

Sec. 807.97 Misbranding by reference to premarket notification.

> Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. **Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.**

FR § 807.97 (emphasis added).

4. California's Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"), Cal. Health & Safety Code §§ 109875-111915, incorporates and mirrors the FDCA, including without limitation, 21 CFR § 807.97. The Sherman Law further provides that "[i]t is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular." Cal. Health & Safety Code § 110390. These regulatory and statutory violations, among others, serve as predicate violations for Plaintiffs' UCL, FAL and CLRA claims asserted herein.

5. The global market for aesthetic procedures is significant. In the United States alone, the American Society of Aesthetic Plastic Surgery, or the ASAPS, estimates that consumers spent approximately $13.5 billion on aesthetic procedures in 2015.[1] Zeltiq markets CoolSculpting extensively throughout North America and Europe to consumers, described more fully below, and advances its deceptive representations through its certification of physicians and technicians who perform the CoolSculpting procedure. Zeltiq uses "targeted marketing programs," including "sales training, practice marketing strategies, and metric analysis," and "partner[s] with [its] customers' practices on marketing, advertising and promotional activities in their local markets to drive demand for

[1] *See* Zeltiq's Form 10-K for the period ending 12/13/16, at page 3.

CoolSculpting."[2]

6. In 2015, Zeltiq launched a direct-to-customer advertising campaign, in order to "enhance and expand [its] brand awareness." This campaign included television commercials, radio spots, digital advertising, print advertising, out-of-home advertising, social media, and public relations.[3]

7. In its advertising, Zeltiq touts the fact that the CoolSculpting system is "FDA cleared," conveying to consumers that the medical device and procedure has the FDA's endorsement that the CoolSculpting system is safe and effective. However, the FDA has promulgated regulations and expressly notified Zeltiq that its premarket clearance "does not in any way denote official approval of the device" and "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97. For example, Zeltiq has made the following claims on its website and in advertisements and marketing materials:

a. "Developed by Harvard scientists, **the CoolSculpting treatment is the only FDA-cleared**, non-surgical fat reduction treatment that uses controlled cooling to eliminate unwanted fat cells."

b. "**Cleared by the FDA**, CoolSculpting works by gently cooling targeted fat cells in the body to induce a natural, controlled elimination of fat cells without affecting surrounding tissue, and the treated fat cells are gone for good."

c. "In the U.S., **the CoolSculpting procedure is FDA-cleared** for the treatment of visible fat bulges in the submental area, thigh, abdomen and flank, along with bra fat, back fat, upper arms, and underneath

[2] *See* Zeltiq's Form 10-K for the period ending 12/13/16, at page 4.
[3] *See* Zeltiq's Form 10-K for the period ending 12/13/16, at pages 4, 17.

the buttocks (also known as banana roll)."[4]

8. Nowhere in Defendants marketing materials and advertising campaign do they ever explain or clarify that CoolSculpting has only been reviewed by the FDA in accordance with premarket notification requirements and has not received the FDA's official approval or endorsement. Nor do Defendants make any attempt in their marketing materials even hint to consumers that 510(k) premarket clearance differs from PMA, or FDA approval.

9. Instead, by stating that CoolSculpting is "[c]leared by the FDA" and "FDA-cleared," Defendants have capitalized on reasonable consumers' lack of understanding of FDA terminology and the vast differences between "approval" and "clearance" in terms of safety, efficacy, trials, testing, etc. Defendants' use of these terms in its marketing materials implies to consumers an official endorsement of its product by the FDA, conduct in which Zeltiq has repeatedly been cautioned by the FDA not to engage.

10. By creating an impression of FDA approval and endorsement as to the safety and efficacy of CoolSculpting to reasonable consumers, Zeltiq is able to command a premium price, increasing consumers' willingness to pay and reduce the market share of competing products, thereby increasing its own sales and profits.

11. Reasonable consumers must, and do, rely on Zeltiq's overall marketing, including, without limitation, television, radio, print media, posters, office displays, and brochures provided to its customers by CoolSculpting-certified physicians and technicians. As such, reasonable consumers remain unaware that they are not receiving treatments that have undergone the rigorous FDA-approval process.

12. If Plaintiffs and Class Members knew that the CoolSculpting system

[4] http://www.coolsculpting.com/

and/or treatments had not undergone the rigorous process of FDA approval, Plaintiffs and Class Members would not have purchased and undergone the procedures or would have paid less for them.

13. By employing the marketing tactics illustrated above, Zeltiq intends for consumers to rely on its representations regarding the FDA's endorsement of CoolSculpting, when in fact no endorsement has been given. Because Zeltiq does not make this distinction in its advertising and marketing, Plaintiffs and Class Members (as well as members of the general public) remain subject to Zeltiq's deceptive advertising.

14. As a result of their reliance on Defendants' omissions and mischaracterizations, consumers have suffered an ascertainable loss of money, including, but not limited to, out of pocket costs incurred in purchasing CoolSculpting procedures. Further, as a result of its deceptive marketing and unfair competition with other similar manufacturers and brands, Zeltiq realized sizable profits.

PARTIES

PLAINTIFF Carmen Otero

15. Plaintiff Carmen Otero is a California citizen who resides in Lakeside, California. During the class period alleged herein, and most recently in or around February 2017, Plaintiff Otero purchased CoolSculpting treatments from LaserAway, a Zeltiq-certified CoolSculpting practice, in San Diego County.

16. Prior to purchasing CoolSculpting treatments, Plaintiff Otero saw, and relied upon, Zeltiq's advertising materials, including displays and brochures provided by Zeltiq to LaserAway, and reviewed Zeltiq's official CoolSculpting website, specifically regarding its representations implying that the device was approved by the FDA. Based on Zeltiq's representations regarding the FDA, Plaintiff Otero reasonably believed that CoolSculpting was approved by the FDA.

17. FDA approval was important to Plaintiff Otero in deciding to

purchase and undergo the CoolSculpting treatments because she reasonably believed that the FDA's approval assured the safety and efficacy of the CoolSculpting devices and procedure. In fact, Defendant's representations indicating the FDA's purported endorsement on Zeltiq's website and throughout its marketing materials were material to Plaintiff Otero in her decision to purchase CoolSculpting treatments.

18. If Zeltiq had disclosed its knowledge of CoolSculpting's lack of FDA approval prior to her purchase, Plaintiff Otero would have seen or heard such representations and been aware of them. If Plaintiff Otero had known at the time of purchase that the CoolSculpting system was not FDA-approved, she would have paid less for the treatments, declined to purchase the treatments, and/or considered alternative treatments that were FDA-approved.

19. Plaintiff Otero would consider purchasing CoolSculpting treatments in the future without the price premium she paid previously while under the reasonable belief that CoolSculpting was FDA-approved, as a result of Zeltiq's representations.

PLAINTIFF Abbey Lerman

20. Plaintiff Abbey Lerman is a California citizen who resides in Los Angeles, California. During the class period alleged herein, and most recently in or around March 2017, Plaintiff Lerman purchased CoolSculpting treatments from Zeltiq-certified CoolSculpting practices in Los Angeles County, including DMH Aesthetics and Dr. David Rahimi (dba Forever Young).

21. Prior to purchasing CoolSculpting treatments, Plaintiff Lerman saw, and relied upon, Zeltiq's online advertising and printed marketing materials, including brochures and videos provided by Zeltiq to its certified practices, and reviewed Zeltiq's official CoolSculpting website, specifically regarding its representations that the device was approved by the FDA. Based on these representations by Zeltiq, Plaintiff Lerman reasonably believed that CoolSculpting

was approved by the FDA.

22. FDA approval was important to Plaintiff Lerman in deciding to purchase and undergo the CoolSculpting treatments because she reasonably believed that the FDA's approval assured the safety and efficacy of the CoolSculpting devices and procedure. In fact, Defendant's representations indicating the FDA's purported endorsement on Zeltiq's website and throughout its marketing materials were material to Plaintiff Lerman in her decision to purchase CoolSculpting treatment.

23. If Zeltiq had disclosed its knowledge of CoolSculpting's lack of FDA approval prior to her purchase, Plaintiff Lerman would have seen or heard such representations and been aware of them. If Plaintiff Lerman had known at the time of purchase that the CoolSculpting system was not FDA-approved, she would have paid less for the treatments, declined to undergo the treatments, and/or considered alternative treatments that were FDA-approved.

24. Plaintiff Lerman would consider purchasing CoolSculpting treatments in the future without the price premium she paid previously while under the reasonable belief that CoolSculpting was FDA-approved, as a result of Zeltiq's representations.

DEFENDANT

25. Defendant Zeltiq Aesthetics, Inc. is a corporation organized and in existence under the laws of the State of Delaware and is registered to do business in the State of California. Zeltiq's corporate headquarters and principal place of business are located at 4410 Rosewood Drive, Pleasanton, CA 94588, in the County of Alameda. Zeltiq tests, produces, manufactures, markets, distributes, and sells CoolSculpting worldwide, nationwide, and throughout California.

26. At all relevant times, Defendant was and is engaged in the business of testing, producing, manufacturing, marketing, distributing, and selling CoolSculpting in Los Angeles County, San Diego County, and throughout the

United States of America.

JURISDICTION

27. This is a class action.

28. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because this action arises under the Constitution or laws of the United States and the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2) and (6), in that, as to each Class defined herein:

a. the matter in controversy exceeds $5,000,000.00, exclusive of interest and costs;

b. this is a class action involving 100 or more class members; and

c. this is a class action in which at least one member of the Plaintiff class is a citizen of a State different from at least one Defendant.

29. The Court has personal jurisdiction over Defendant, which has at least minimum contacts with the State of California because it has conducted business there and has availed itself of California's markets through the designing, manufacturing, constructing, assembling, advertising, distributing, and selling of CoolSculpting.

VENUE

30. Zeltiq, through its business of advertising, distributing, and selling CoolSculpting, has established sufficient contacts in this district such that personal jurisdiction is appropriate. Defendant is deemed to reside in this district pursuant to 28 U.S.C. § 1391(a).

31. In addition, a substantial part of the events or omissions giving rise to these claims and a substantial part of the property that is the subject of this action are in this district. In addition, Plaintiff Lerman's Declaration, as required under California Civil Code section 1780(d) (but not pursuant to *Erie* and federal procedural rules), reflects that a substantial part of the events or omissions giving rise to the claims alleged herein occurred, or a substantial part of property that is

the subject of this action, is situated in Los Angeles County, California. It is attached as **Exhibit 1.**

32. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a).

FACTUAL ALLEGATIONS

33. The global market for aesthetic procedures is significant. In the United States alone, consumers spent approximately $13.5 billion on aesthetic procedures in 2015, according to Zeltiq's 2016 Annual Report. Zeltiq markets CoolSculpting extensively throughout North America, specifically touting CoolSculpting's FDA clearance. In fact, Zeltiq's entire marketing strategy seems to revolve around its emphasis of the FDA's purported endorsement of its medical device.

34. By stating that CoolSculpting is "FDA-cleared" throughout its marketing materials to consumers and its website, Defendants have capitalized on reasonable consumers' understanding (or lack thereof) of FDA terminology. Reasonable consumers, like Plaintiffs, do not know and are not informed by Zeltiq of the vast differences between "FDA approval" through a Premarket Approval Application (PMA) and "FDA 510(k) premarket clearance" or simply "FDA clearance," especially as it concerns the FDA's review of the safety, efficacy, clinical trials, and testing results of CoolSculpting. Thus, Zeltiq has misbranded CoolSculpting pursuant to 21 CFR § 807.97:

> Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, ***does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding***. (emphasis added).

35. The FDA warned Zeltiq since at least 2009, in every premarket notification letter to Zeltiq, that the "**FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. […] Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97)**."[5]

36. The Medical Device Amendments of 1976 to the FDCA established three "classes" of medical devices: Class I, II, and III. "The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective."[6] A post-1976 medical device is automatically placed into Class III and is subject to premarket approval requirements, including the FDA's independent "scientific review to ensure the safety and effectiveness" of the device. However, manufacturers can avoid the FDA's thorough scientific review and approval process by submitting a 510(k) Premarket Notification for "FDA clearance" to market the device based on its similarities to pre-1976 devices.

37. Therefore, it behooves a manufacturer to link their "new" medical device to a pre-1976 device, to avoid costly and time-consuming FDA review and get their products to the market quicker. Medical devices that go through this less stringent, fast-tracked FDA review process attain 510(k) clearance. By contrast, PMA is extremely rigorous, and requires a manufacturer to present the FDA with "all information" known or reasonably knowable about the device, including detailed information about the design, manufacture, uses, and labeling of the device. To obtain PMA approval of a medical device, the FDA must find that the medical device has *sufficient scientific evidence showing the device is safe and*

[5] FDA 510(k) Premarket Notification Database, Search for Zeltiq, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

[6] https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm

effective for its intended use. Only then is a medical device manufacturer permitted to use the term "FDA-approved" in its marketing of a medical device.

38. The significant evidence needed to obtain FDA-approval of a medical device is not required when a medical device manufacturer applies for FDA review via the 510(k) premarket notification process. Section 510(k) of the FDCA allows manufacturers, like Zeltiq, to submit a "summary" to the FDA "describing" how its medical device is "substantially equivalent" to a pre-1976 device and the intended use of the device.

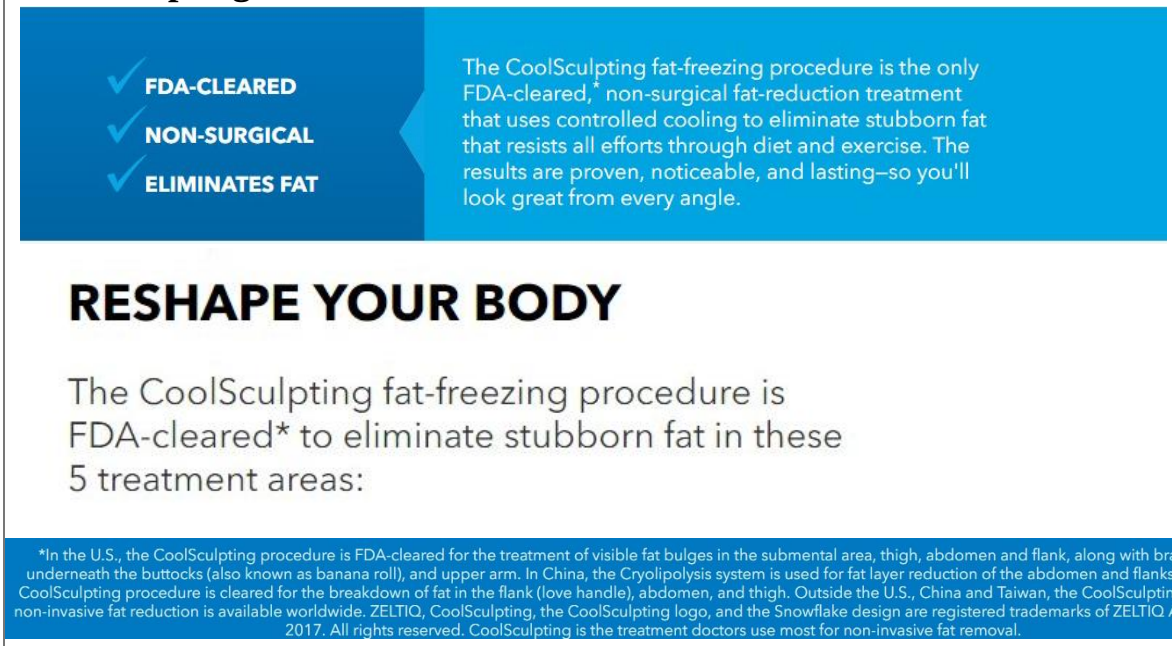
39. In September 2010, the FDA found Zeltiq's "Dermal Cooling Device," later "CoolSculpting," substantially equivalent to pre-1976 Class II medical devices that are "a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells for non-invasive aesthetic use." At that time, the FDA advised Zeltiq that "persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the focused ultrasound device they intend to market and receive clearance, prior to marketing their device." At no point did the FDA perform the rigorous, independent testing to ensure safety and effectiveness of CoolSculpting required through Premarket Approval and, as such, the FDA has not endorsed or approved the safety and effectiveness of CoolSculpting.

40. In defiance of the FDCA, and the FDA's unequivocal admonitions regarding misbranding and misleading statements as to FDA endorsement, Zeltiq has chosen to include reference to its "FDA clearance" in virtually *all* of its advertising and consumer-facing marketing materials, deceptively implying to consumers that the FDA has approved or otherwise endorsed CoolSculpting's safety and effectiveness for its stated purposes. Further, Zeltiq never clarifies, explains, or even attempts to inform consumers that "FDA clearance" is *not* equivalent to the widely-known and understood "FDA approval." Rather, Zeltiq

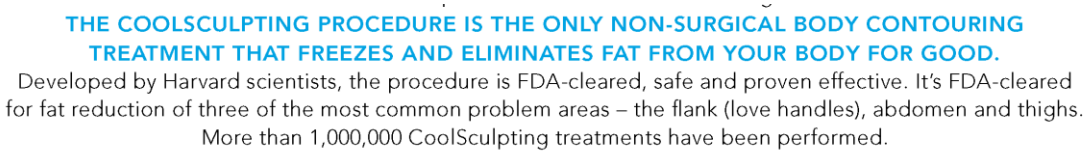
ensures that the words "safe" and "effective" are depicted immediately next to its reference to the FDA.

41. Some examples of Zeltiq's misleading advertisements from its website and marketing materials are shown below. Zeltiq further provides its own "In the Media" page for consumers to view articles and reviews published by popular news outlets, presumably following Zeltiq's own review of the article's accuracy.

CoolSculpting.com



CoolSculpting Official Advertisement – "A Sculpted Summer You"



CoolSculpting.com FAQS:

IS THE COOLSCULPTING PROCEDURE SAFE? –

The CoolSculpting procedure is FDA-cleared for the treatment of visible fat bulges in the submental area, thigh, abdomen, and flank. As the #1 non-invasive fat reduction procedure and with millions of CoolSculpting procedures performed worldwide, it is proven to be a safe and effective treatment.*

CoolSculpting LinkedIn:

About us

The CoolSculpting fat-freezing procedure is the only FDA-cleared,* non-surgical fat-reduction treatment that uses controlled cooling to eliminate stubborn fat that resists all efforts through diet and exercise. The results are proven, noticeable, and lasting—so you'll look great from every angle.

CoolSculpting.com "In The Media" - Coolsculpting.com/in-the-media/

A Slimmer Waistline, Trimmer Hips—No Surgery Necessary

Another new body-contouring option is Zeltiq, a machine that uses intense cold to destroy fat cells (which are more vulnerable to freezing temperatures than surrounding tissue). Like the ultrasound treatment, Zeltiq requires no needles, incisions, anesthesia, or recovery time. It's already FDA approved to cool the skin during other dermatologic procedures, and some doctors are starting to use it off-label to reduce fat. "These technologies are still in the early stages, but they will be perfected over the next decade and we will finally have the ability to eliminate fat without surgery," says Sadick. Big caveat: UltraShape and Zeltiq are not designed to remove large volumes of fat; doctors stress that the machines are most effective on areas of "localized fat," like love handles or back bulges.

"Zeltiq requires no needles, incisions, anesthesia, or recovery time. It's already FDA-approved to cool the skin during other dermatologic procedures, and some doctors are starting to use it off-label to reduce fat." – Oprah Magazine, May 2010

SHOP

MICRO WAVE

THIGH MASTER

A proven liposuction alternative can finally be used on the thighs: CoolSculpting, the fat-freezing technology that cryogenically kills adipose cells, launched circa 2010 with a suction-cup applicator designed to suck the targeted area against the cooling panels. The technology is incredibly effective (Alexiades-Armenakas estimated a 25 percent reduction in fat cells per treated zone), but the cups' shape made it impossible to treat love handles or the inner or outer thighs. The flat-headed panel of the recently FDA-approved CoolSmooth works just as well as the original

ELLE

LORDE

475+

"The flat-headed panel of the recently FDA-approved Cool Smooth [a CoolSculpting device] …" – Elle Magazine, Oct. 2014


ELLE

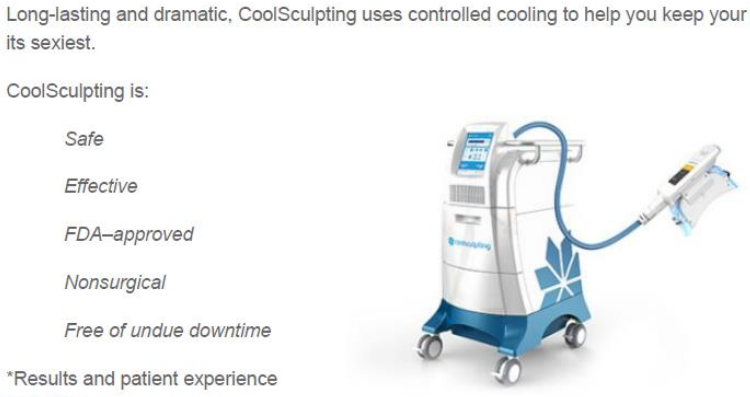
WHY I FROZE THE FAT OFF MY THIGHS

"I decided to try a new FDA-approved procedure called CoolSculpting…86 percent of the patients in the FDA trials claimed to see a visible reduction in their thigh fat four months after receiving the treatment." – Elle Magazine, Nov. 2014

"CoolSculpting … is going beyond the stomach and was just approved by the FDA for fat reduction on the thighs." – Allure Magazine, July 2015

42. Further, Zeltiq advances its misbranding of CoolSculpting by failing to explain "FDA clearance" to the physicians and technicians who attend its CoolSculpting University to become a "certified" practice. The following pictures were taken from CoolSculpting's website and the websites of its "certified" practices, accessed through CoolSculpting.com, further evidencing the deception and lack of clarification regarding "FDA clearance."

LaserAway.com – a Certified CoolSculpting Practice:


Long-lasting and dramatic, CoolSculpting uses controlled cooling to help you keep your figure its sexiest.

CoolSculpting is:

Safe

Effective

FDA–approved

Nonsurgical

Free of undue downtime

*Results and patient experience may vary.

Mirror Mirror Beauty Boutique – a Certified CoolSculpting Practice:

What is Coolsculpting?

CoolSculpting is the first and only FDA-cleared method for successfully eliminating stubborn body fat without surgery. The procedure utilizes cold temperatures; freezing away the pockets of fatty tissue that are difficult to address through diet and exercise alone. The results from CoolScultping are safe, dramatic, and long lasting.

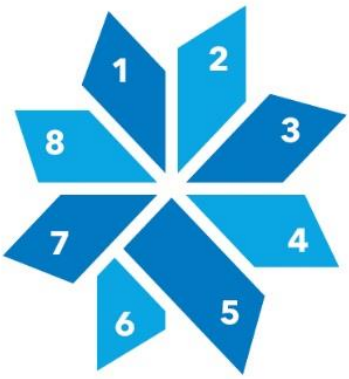
Mirror Mirror Beauty Boutique - FAQS

• Is CoolSculpting safe? CoolSculpting has been cleared by the Food and Drug Administration (FDA) as a safe and effective method for the reduction of fatty deposits. As there are no incisions, CoolSculpting holds little chance for complications to occur.

CoolSculpting.com "For Physicians" - CoolSculptingHCP.com/fat-freezing-science/proven-results/

The Differences Are Easy to See

Snowflakes are unique. This one can't be imitated.



1 | The First
More than 5 U.S. and 48 international patents secured, with 19 U.S. and 80 international patents pending ZELTIQ IP

2 | The Most Respected
FDA-cleared in the United States, CE marked as a Class IIa medical device and has additional medical approvals worldwide

3 | The Most Proven
Scientific evidence published in more than 60 peer-reviewed abstracts and papers

43. Zeltiq acknowledges that "FDA clearance" is a selling point – both implicitly by the prominent use of this in their advertising, and explicitly in a recent lawsuit filed against competitors whose products Zeltiq alleges are "falsely touted as providing the same treatments as Zeltiq's CoolSculpting device" and are described "using explicit references to facts that apply exclusively to Zeltiq, such as 'patented,' 'clinically proved' or 'FDA-approved.'"[7]

[7] *Zeltiq Aesthetics, Inc. vs. Total Body Laser Skin Care LLC et al.*, 16-cv-00793 (W.D. Wisc., December 1, 2016)

44. Zeltiq provides a great deal of support and training to the direct purchasers of the CoolSculpting system. Zeltiq conducts on-location training to clinic and spa providers, and offers more intensive training to providers at "CoolSculpting University." Zeltiq employs a team of "Practice Development Managers" to "assist[] practices to market CoolSculpting to patients" and train customers on "practice enhancement execution protocols" including "branding, grassroots initiatives and digital marketing tactics."[8] Thus, Zeltiq's deceptive messaging about its FDA clearance is passed along to its direct customers and ultimately to patients.

45. By creating an impression of FDA approval and endorsement as to the safety and efficacy of CoolSculpting to reasonable consumers, Zeltiq is able to command a premium price, increasing consumers' willingness to pay and reduce the market share of competing products, thereby increasing its own sales and profits.

46. Reasonable consumers must, and do, rely on Zeltiq's overall marketing, including, without limitation, television, radio, print media, posters, office displays, and brochures provided to its customers by CoolSculpting-certified physicians and technicians. As such, reasonable consumers remain unaware that they are not receiving treatments that have undergone the rigorous FDA-approval process.

47. Defendants' deceptive marketing also poses a serious health concern and safety risk to consumers. By implying that CoolSculpting has been endorsed by the FDA, and therefore has undergone the numerous studies, tests, and trials required for FDA approval, Zeltiq is putting consumers at risk

48. By employing the marketing tactics illustrated above, Zeltiq intends for consumers to rely on its representations regarding the FDA approval status of

[8] Form 10-K at 9.

CoolSculpting rather than the much less rigorous process for FDA clearance.

49. Because Zeltiq does not make this distinction in its advertising and marketing, Plaintiffs and Class Members (as well as members of the general public) remain subject to Zeltiq's deceptive advertising and misrepresentations.

50. By employing the marketing tactics illustrated above, Zeltiq intends for consumers to rely on its representations regarding the FDA's endorsement of CoolSculpting, and thousands of reasonable consumers did in fact so rely.

51. If Plaintiffs and Class Members knew that CoolSculpting was not FDA-approved, Plaintiffs and Class Members would not have purchased the CoolSculpting treatments or would have paid less for them.

52. Zeltiq knows, or should reasonably know, that consumers purchase CoolSculpting, in part, because of the supposed endorsement by the FDA, and knows that consumers will, and do, pay a premium for these treatments, and/or would not purchase them at all without FDA-approval.

53. As a result of their reliance on Defendants' representations, consumers have suffered an ascertainable loss of money, including, without limitation, out of pocket costs incurred in purchasing CoolSculpting. Further, as a result of its deceptive marketing and unfair competition with similar manufacturers and brands who do not tout FDA clearance, despite having received it in order to market its device, Zeltiq realized sizable profits.

54. As the intended, direct, and proximate result of Zeltiq's false, misleading, and deceptive representations and omissions, Zeltiq has been unjustly enriched through more sales of CoolSculpting and higher profits at the expense of Plaintiffs and the Class Members.

CLASS ALLEGATIONS

55. Plaintiffs bring this lawsuit as a class action on behalf of themselves and all others similarly situated as members of the proposed Class pursuant to pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and

23(c)(4). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

56. The Class and Sub-Class are defined as:

> **Nationwide Class**: All individuals in the United States who purchased one or more CoolSculpting treatments from four years prior to the filing of this complaint through the date of certification (the "Nationwide Class" or "Class").
>
> **California Sub-Class**: All members of the Nationwide Class who reside in the State of California.
>
> **CLRA Sub-Class**: All members of the California Sub-Class who are "consumers" within the meaning of California Civil Code § 1761(d).

57. Excluded from the Class and Sub-Classes are: (1) Defendants, any entity or division in which Defendants have a controlling interest, and their legal representatives, officers, directors, assigns, and successors; (2) the Judge to whom this case is assigned and the Judge's staff; (3) any Judge sitting in the presiding state and/or federal court system who may hear an appeal of any judgment entered; and (4) those persons who have suffered personal injuries as a result of the facts alleged herein. Plaintiffs reserve the right to amend the Class and Sub-Class definitions if discovery and further investigation reveal that the Class and Sub-Class should be expanded or otherwise modified.

58. Numerosity: Although the exact number of Class Members is uncertain and can only be ascertained through appropriate discovery, the number is great enough such that joinder is impracticable. The disposition of the claims of these Class Members in a single action will provide substantial benefits to all parties and to the Court. The Class Members are readily identifiable from information and records in Defendants' possession, custody, or control.

59. Typicality: Plaintiffs' claims are typical of the claims of the Class in that Plaintiffs, like all Class Members, were deceived by Zeltiq's statements regarding the FDA. The representative Plaintiffs, like all Class Members, have been damaged by Defendant's misconduct in that they have incurred the over-

valued costs of purchasing a CoolSculpting treatment for a premium price in reliance on Zeltiq's representations. Furthermore, the factual bases of Zeltiq's misconduct are common to all Class Members and represent a common thread resulting in injury to all Class Members.

60. Commonality: There are numerous questions of law and fact common to Plaintiffs and the Class that predominate over any question affecting only individual Class Members. These common legal and factual issues include the following:

a. Whether Zeltiq misrepresented and/or failed to disclose material facts concerning its CoolSculpting system;

b. Whether the CoolSculpting system and treatments are misbranded under federal and/or state laws;

c. Whether Zeltiq's conduct was unlawful, unfair and/or deceptive;

d. Whether Zeltiq has a duty to disclose the true nature of the FDA's involvement with or approval of CoolSculpting and the distinction between clearance and approval;

e. Whether Plaintiffs and other Class Members are entitled to equitable relief, including but not limited to a preliminary and/or permanent injunction;

f. Whether Plaintiffs and other Class Members are entitled to damages;

g. Whether Defendants knew or reasonably should have known of their deceptive representations and omissions relating to its CoolSculpting system; and

h. Whether Defendants are obligated to inform Class Members of their right to seek reimbursement for having paid for CoolSculpting treatments in reliance on Defendants' misrepresentations.

61. Adequate Representation: Plaintiffs will fairly and adequately protect the interests of the Class Members. Plaintiffs have retained attorneys

experienced in the prosecution of class actions, including consumer and product defect class actions, and Plaintiffs intend to prosecute this action vigorously.

62. Predominance and Superiority: Plaintiffs and Class Members have all suffered and will continue to suffer harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. Absent a class action, most Class Members would likely find the cost of litigating their claims prohibitively high and would therefore have no effective remedy at law. Because of the relatively small size of the individual Class Members' claims, it is likely that only a few Class Members could afford to seek legal redress for Defendants' misconduct. Absent a class action, Class Members will continue to incur damages, and Defendants' misconduct will continue without remedy. Class treatment of common questions of law and fact would also be a superior method to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the courts and the litigants, and will promote consistency and efficiency of adjudication.

FIRST CAUSE OF ACTION

(Violation of California's Consumers Legal Remedies Act, California Civil Code § 1750, et seq.,)

63. Plaintiffs incorporate by reference the allegations contained in each and every paragraph of this Complaint.

64. Plaintiffs bring this cause of action on behalf of themselves and on behalf of the members of the CLRA Sub-Class.

65. Defendants are a "person" as defined by California Civil Code § 1761(c).

66. Plaintiffs and CLRA Sub-Class Members are "consumers" within the meaning of California Civil Code § 1761(d) because they bought the CoolSculpting treatments for personal use.

67. By failing to disclose to Plaintiffs and prospective Class Members and concealing the true and actual nature of the FDA's review of the CoolSculpting system and the resulting premarket clearance of the device, Defendants violated California Civil Code § 1770(a), as they represented that the CoolSculpting system had characteristics and benefits that it does not have, represented that the CoolSculpting system was of a particular standard, quality, or grade when it was of another, and advertised the CoolSculpting system with the intent not to sell the CoolSculpting treatments as advertised. See Cal. Civ. Code §§ 1770(a)(5)(7) & (9).

68. Defendant's deceptive acts or practices occurred repeatedly in Defendants' trade or business and were capable of deceiving a substantial portion of the purchasing public.

69. Defendants knew the CoolSculpting system did not possess the characteristics and benefits as represented and were not of the particular standard, quality or grade as represented.

70. As a result of their reliance on Defendants' representations and omissions, Class Members suffered an ascertainable loss of money, property, and/or value of their CoolSculpting procedures.

71. Defendants were under a duty to Plaintiffs and Class Members to disclose the true and actual nature of the FDA's review and clearance of CoolSculpting because:

a. Defendants were in a superior position to know the true nature of the FDA's review of the CoolSculpting system;

b. Plaintiffs and Class Members could not reasonably have been expected to know the distinction between FDA clearance and FDA approval; and

c. Defendants knew that Plaintiffs and Class Members could not reasonably have been expected to know the distinction between FDA

clearance and FDA approval;

72. In failing to disclose and misrepresenting the true nature of the FDA's clearance of CoolSculpting, Defendants knowingly and intentionally concealed material facts and breached their duty not to do so.

73. The facts Defendants concealed from or misrepresented to Plaintiffs and Class Members are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase the CoolSculpting treatments or pay less. If Plaintiffs and Class Members had known that the CoolSculpting system was not FDA-approved, they would not have purchased the CoolSculpting treatments or would have paid less for them.

74. Plaintiffs and Class Members are reasonable consumers who expect manufacturers, like Zeltiq, to provide accurate and truthful representations regarding the safety and efficacy of their products. Further, reasonable consumers, like Plaintiffs, rely on the representations made by manufacturers regarding the safety and efficacy of their medical devices in determining whether to purchase and consider that information important to their purchase decision.

75. As a direct and proximate result of Defendants' unfair methods of competition and/or unfair and deceptive practices, Plaintiffs and the Class have suffered and will continue to suffer actual damages.

76. Plaintiffs and the Class are entitled to equitable relief.

77. Plaintiffs provided Defendants with notice of its violations of the CLRA pursuant to California Civil Code § 1782(a). Defendants failed to provide appropriate relief for its violations of the CLRA within 30 days. Therefore, Plaintiffs now seek monetary, compensatory, and punitive damages, in addition to injunctive and equitable relief.

SECOND CAUSE OF ACTION

(Violation of California Business & Professions Code § 17500 et seq.)

78. Plaintiffs incorporate by reference the allegations contained in each and every paragraph of this Complaint.

79. Plaintiffs bring this cause of action on behalf of themselves and on behalf of the Nationwide Class, or in the alternative, on behalf of the California Sub-Class.

80. California Business & Professions Code § 17500 prohibits unfair, deceptive, untrue, and misleading advertising in connection with the disposal of personal property (among other things), including, without limitation, false statements as to the use, worth, benefits, or characteristics of the property.

81. Defendants have committed acts of untrue and misleading advertising by engaging in false representations as to the true nature of the FDA's review and approval of CoolSculpting in violation of the FDCA per 21 CFR § 807.97, which states that "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding", and Cal. Health & Safety Code § 110390 which provides that "[i]t is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular." In addition, Defendants made such untrue or misleading advertisements with the intent to dispose of said products and/or services.

82. Defendants knew, or in the exercise of reasonable care should have known, that these representations were misleading and deceptive. Defendants' misleading representations and omissions regarding CoolSculpting were, and continue to be, likely to deceive members of the public.

83. As a result of their reliance on Defendants' misrepresentations and omissions, Class Members suffered an ascertainable loss of money, property,

and/or value of their CoolSculpting treatments.

84. As a direct and proximate result of Defendants' unfair and deceptive practices, Plaintiffs and the Class have suffered and will continue to suffer actual damages.

85. Defendants have been unjustly enriched and should be required to make restitution to Plaintiffs and the Class. Pursuant to § 17535 of the Business & Professions Code, Plaintiffs and Class Members are entitled to an order of this Court enjoining such future conduct on the part of Zeltiq, and such other orders and judgments which may be necessary to disgorge Zeltiq's ill-gotten gains and restore to any person in interest any money paid for its CoolSculpting devices and/or treatments as a result of the wrongful conduct of Zeltiq.

THIRD CAUSE OF ACTION

(Violation of California Business & Professions Code § 17200 et seq.)

86. Plaintiffs incorporate by reference the allegations contained in each and every paragraph of this Complaint.

87. Plaintiffs bring this cause of action on behalf of themselves and on behalf of the Nationwide Class, or in the alternative, on behalf of themselves and on behalf of the California Sub-Class.

88. As a result of their reliance on Defendants' misrepresentations and omissions, Class Members suffered an ascertainable loss of money, property, and/or value of their CoolSculpting treatments.

89. California Business & Professions Code § 17200 prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

90. Defendants' acts, conduct and practices were unlawful, in that they constituted:

a. Violations of California's Consumers Legal Remedies Act;

b. Violations of California's False Advertising Law;

c. Violations of the Federal Food Drug & Cosmetic Act; and

d. Violations of California's Sherman Food, Drug, and Cosmetic Law.

91. Plaintiffs and Class Members are reasonable consumers who expect manufacturers, like Zeltiq, to provide lawful, accurate, and truthful representations regarding the safety and efficacy of their products as well as official endorsements indicating such. Further, reasonable consumers, like Plaintiffs, rely on the representations made by manufacturers regarding the safety and efficacy of products, particularly medical devices and treatments, in determining whether to purchase, and consider that information important to their purchase decision.

92. In failing to disclose and actively misrepresenting the true nature of the FDA's clearance of CoolSculpting, Defendants have knowingly and intentionally misrepresented and concealed material facts and breached its duty not to do so. Defendants were under a duty to Plaintiffs and Class Members to disclose the distinction between "FDA Approval" and "FDA Clearance" and the true nature of the FDA's review of CoolSculpting, because:

a. Defendants were in a superior position to know the true nature of FDA clearance;

b. Defendants made partial representations about the FDA's involvement with the CoolSculpting system without revealing the material information needed to determine whether to purchase; and

c. Defendants actively concealed the true nature of the FDA's involvement with the CoolSculpting system from Plaintiffs and the Class.

93. The facts Defendants concealed from or misrepresented to Plaintiffs and Class Members are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase CoolSculpting procedures or pay less. If Plaintiffs and Class Members had known that the CoolSculpting system was not FDA-approved, they would not have purchased

CoolSculpting treatments or would have paid less for them.

94. Defendants' conduct was and is likely to deceive consumers.

95. By their conduct, Defendants have engaged in unfair competition and unlawful, unfair, and fraudulent business practices.

96. Defendants' unlawful, unfair or deceptive acts or practices occurred repeatedly in Defendants' trade or business, and were capable of deceiving a substantial portion of the purchasing public.

97. As a direct and proximate result of Defendants' unlawful, unfair and deceptive practices, Plaintiffs and the Class have suffered and will continue to suffer actual damages.

98. Defendants have been unjustly enriched and should be required to make restitution to Plaintiffs and the Class pursuant to §§ 17203 and 17204 of the Business & Professions Code.

PRAYER FOR RELIEF

99. Plaintiffs, on behalf of themselves, and all others similarly situated, request the Court to enter judgment against Defendants, as follows:

a. An order certifying the proposed Class and Sub-Classes, designating Plaintiffs as named representatives of the Class, and designating the undersigned as Class Counsel;

b. An order enjoining Defendants from further deceptive advertising, sales, and other business practices with respect to its representations regarding the CoolSculpting system and treatments;

c. An injunction:

i. Ordering Defendants to cease using "FDA cleared" and similar language on its website and in its advertisements and other marketing materials; or

ii. Ordering Defendants to disclose, anytime "FDA cleared" or similar language is used, the distinction between FDA

clearance and FDA approval;

d. A declaration requiring Defendants to comply with the various provisions of the Federal Food Drug & Cosmetic Act, California's False Advertising Law and CLRA alleged herein and to make all the required representations;

e. An award to Plaintiffs and the Class for compensatory, exemplary, and statutory damages, including interest, in an amount to be proven at trial;

f. A declaration that Defendants must disgorge, for the benefit of the Class, all or part of the ill-gotten profits it received from the sale of its CoolSculpting system and treatments, or make full restitution to Plaintiffs and Class Members;

g. An award of attorneys' fees and costs, as allowed by law;

h. An award of attorneys' fees and costs pursuant to California Code of Civil Procedure § 1021.5;

i. An award of pre-judgment and post-judgment interest, as provided by law;

j. Leave to amend the Complaint to conform to the evidence produced at trial; and

k. Such other relief as may be appropriate under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury of any and all issues in this action so triable.

Dated: July 20, 2017

Respectfully submitted,

Capstone Law APC

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